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Atty. Dkt. No. 071949-1314

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Kenneth F. Buechler

Title: DIAGNOSTIC DEVICES AND APPARATUS FOR THE CONTROLLED MOVEMENT OF REAGENTS WITHOUT MEMBRANES

Appl. No.: 09/805,653

Filing Date: March 13, 2001

Examiner: L. Alexander

Art Unit: 1743

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on the date below.

Jodie Price
(Printed Name)

(Signature)

April 11, 2002
(Date of Deposit)

TRANSMITTAL

Commissioner for Patents
Box:
Washington, D.C. 20231

Sir:

Transmitted herewith is:

☒ Response to Office Action; and

☒ Change of Correspondence Address.

☒ The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872 (Order No. 071949-1314). Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872 (Order No. 071949-1314).

Please direct all correspondence to the undersigned attorney or agent at the address indicated below.

Respectfully submitted,

Date April 11, 2002

By _____
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Docket No. 071949-1314
Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Kenneth F. Buechler

Serial No.: 09/805,653

Filed: March 13, 2001

For: DIAGNOSTIC DEVICES AND APPARATUS FOR THE CONTROLLED MOVEMENT OF REAGENTS WITHOUT MEMBRANES

Examiner: Alexander, Lyle

Group Art Unit: 1743

RESPONSE TO OFFICE ACTION

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action mailed on January 11, 2002 ("Paper No. 7"), please consider the following remarks.

The invention relates to devices for conducting assays, including qualitative, semi-quantitative and quantitative determinations of a plurality of analytes in a single test format. Claims 74-100 are currently pending in the application. Applicants respectfully request reconsideration of the claimed invention in view of the following remarks.

Non Art-Based Remarks

Claim Rejections – 35 U.S.C. § 112, Second Paragraph

Applicant respectfully traverses the rejection of claims 74-100 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for failing to particular point out and distinctly claim the subject matter which applicant regards as the invention. this rejection.

When determining definiteness, the proper standard to be applied is "whether one skilled in the art would understand the bounds of the claim when read in the light of the specification." *Credle v. Bond*, 30 USPQ2d 1911, 1919 (Fed. Cir. 1994). See also *Miles Laboratories, Inc. v. Shandon, Inc.*, 27 USPQ2d 1123, 1127 (Fed. Cir. 1993) ("If the claims read in the light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more.") (emphasis added).

Applicant respectfully disagrees with the Examiner's assertion that it is allegedly unclear how the plurality of capture zones contact the sample. It is respectfully submitted that claim 74 clearly recites that the assay devices of the presently claimed invention comprise a diagnostic element comprising a capillary space through which the sample flows. A non-absorbent surface comprising a plurality of discrete capture zones is within the capillary space. Thus, one of ordinary skill in the art would reasonably understand that the sample would contact the plurality of capture zones as it flowed through the capillary space.

Applicant respectfully submits that, because the claims reasonably apprise those skilled in the art of the scope of the invention, the requirements of 35 U.S.C. § 112, second paragraph, have been met. Applicant, therefore, respectfully requests that the rejection be reconsidered and withdrawn.

Art-Based Remarks

35 U.S.C. § 102

Applicant respectfully traverses the rejection of claims 74-100 under 35 U.S.C. §102 (b), as allegedly being anticipated by Hillman et al., U.S. Patents 4,756,884 or 4,948,961 ("the Hillman patents").

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. Furthermore, the claims must be interpreted in light of the teaching of the specification. In re Bond, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). See also MPEP §2131.

The instant claims relate to an assay device for determining the presence or amount of a plurality of target ligands in a sample. The claimed assay devices comprise a diagnostic element comprising a capillary space in which a non-absorbent surface contains a plurality of discrete capture zones. Each discrete capture zone comprising a capture element that binds one target ligand in said plurality of target ligands. No such devices are disclosed in the cited Hillman patents.

For example, the Hillman patents disclose an analytical device for detecting the presence of an analyte in a sample. In those embodiments in which more than one signal is detected by immobilization of an analyte on a device surface, the Hillman patents disclose separating the flow into multiple capillary spaces, none of which detects more than a single analyte. *See, e.g.*, description of figure 4 in the '961 patent, column 21, lines 37-68 ("Chamber 28 is divided into two half chambers... 136 and 138."). Thus, the Hillman patents do not disclose any assay devices comprising a plurality of discrete capture zones on a single non-absorbent surface in a capillary space for determining the presence or amount of a plurality of target ligands in a sample, as provided by the instant claims.

Furthermore, Applicant respectfully disagrees with the Examiner's contention that the Hillman patents "contain the claimed beads functionalized by haptens, ligands, antibodies, or enzymes which read on the claimed capture elements." Paper No. 7, page 2. The present claims refer to "a non-absorbent surface comprising a plurality of discrete capture zones." Nothing in the Hillman patents indicates that any one "bead" contains a plurality of discrete capture zones for different analytes. Moreover, no other single non-absorbent surface contains a plurality of discrete capture zones, as the "beads" disclosed by the Hillman patents are "included in the medium" ('961 patent, column 10, lines 20-58) so that they may be crosslinked for detection; thus, these beads are not immobilized on a surface as discrete capture zones. *See, e.g.*, description of figure 3 in the '961 patent, column 20, line 47, through column 21, line 24 (For the detection of multiple analytes, beads in chamber 108 bind to a common epitope. In each of three separate chambers 96, 98, and 100, beads corresponding to individual serotype antigens are used

to agglutinate the beads originating in (and flowing from) chamber 108 if that serotype is present in the original sample. Detection of another (undisclosed) anaylte in the sample may take place in yet another chamber 106).

Thus, the Hillman patents make it clear that any detection of multiple analytes must occur in separate spaces, and not in a common capillary space comprising a plurality of discrete capture zones on a surface. Moreover, the "particles" recited in present claims 79 *et seq.* are immobilized on discrete capture zones. In contrast, the detection of beads contemplated by the Hillman patents requires that the beads be free to flow in the device, and not immobilized on a surface. *See, e.g.*, '961 patent, column 12, lines 9-29.

Therefore, because the Hillman patents do not teach and suggest every limitation of the claimed invention, the claims in the instant application are not anticipated by the cited patents. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §102(b) be reconsidered and withdrawn.

CONCLUSION

In view of the above remarks, Applicant respectfully submits that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the telephone number listed below so that they may be resolved without the need for an additional action.

Respectfully submitted,
FOLEY & LARDNER

Dated: April 11, 2002

By: _____
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